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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,340	06/23/2003	Birthe Lykkegaard Hansen	6454.504-US	2007

23650 7590 12/21/2005

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EXAMINER	
MOORE, WILLIAM W	

ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 12/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/602,340	HANSEN ET AL.	
	Examiner	Art Unit	
	William W. Moore	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 August 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-29* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. §§ 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claims 1-29, each drawn in part to an aqueous liquid composition comprising a human or bovine or bovine factor VII polypeptide modified by an amino acid substitution at position Ser344, to a first method of making the composition, and to a method of use of the composition in the inhibition of a tissue factor mediated reaction in a subject.

Group 2, claims 1-24 and 26-29, each drawn in part to an aqueous liquid composition comprising a human or bovine factor VII polypeptide modified by an amino acid substitution at position Lys341, to a first method of making the composition, and to a method of use of the composition in the inhibition of a tissue factor mediated reaction in a subject.

Group 3, claims 1-24 and 26-29, each drawn in part to an aqueous liquid composition comprising a human or bovine factor VII polypeptide modified by an amino acid substitution at position Asp242, to a first method of making the composition, and to a method of use of the composition in the inhibition of a tissue factor mediated reaction in a subject.

Group 4, claims 1-29, each drawn in part to an aqueous liquid composition comprising a human or bovine factor VII polypeptide modified by an amino acid substitution at position His193, to a first method of making the composition, and to a method of use of the composition in the inhibition of a tissue factor mediated reaction in a subject.

Group 5, claims 1-29, each drawn in part to an aqueous liquid composition comprising a human or bovine factor VII polypeptide having an active site modified by a reaction with a peptide chloromethylketone, to a first method of making the composition, and to a method of use of the composition in the inhibition of a tissue factor mediated reaction in a subject.

Group 6, claims 1-24 and 26-29, each drawn in part to an aqueous liquid composition comprising a human or bovine factor VII polypeptide having an active site modified by a reaction with an azapeptide, to a first method of making the composition, and

to a method of use of the composition in the inhibition of a tissue factor mediated reaction in a subject.

Group 7, claims 1-24 and 26-29, each drawn in part to an aqueous liquid composition comprising a human or bovine factor VII polypeptide having an active site modified by a reaction with a guanidobenzoate derivative agent, to a first method of making the composition, and to a method of use of the composition in the inhibition of a tissue factor mediated reaction in a subject.

Group 8, claims 1-24 and 26-29, each drawn in part to an aqueous liquid composition comprising a human or bovine factor VII polypeptide having an active site modified by a reaction with a 3-alkyloxy-4-chloroisocoumarin agent, to a first method of making the composition, and to a method of use of the composition in the inhibition of a tissue factor mediated reaction in a subject.

Group 9, claims 1-24 and 26-29, each drawn in part to an aqueous liquid composition comprising a human or bovine factor VII polypeptide having an active site modified by a reaction with a sulfonyl flouride, to a first method of making the composition, and to a method of use of the composition in the inhibition of a tissue factor mediated reaction in a subject.

Group 10, claims 1-24 and 26-29, each drawn in part to an aqueous liquid composition comprising human or bovine factor VII polypeptide having an active site modified by a reaction with diisopropylfluorophosphate (DFP), to a first method of making the composition, and to a method of use of the composition in the inhibition of a tissue factor mediated reaction in a subject.

Group 11, claims 1-24 and 26-29, each drawn in part to an aqueous liquid composition comprising human or bovine factor VII polypeptide having an active site modified by a reaction with tosylpropylchloromethyl ketone (TPCK), to a first method of making the composition, and to a method of use of the composition in the inhibition of a factor mediated reaction in a subject.

Group 12, claims 1-24 and 26-29, each drawn in part to an aqueous liquid composition comprising human or bovine factor VII polypeptide having an active site modified by a reaction with tosylysylchloromethyl ketone (TLCK), to a first method of making the composition, and to a method of use of the composition in the inhibition of a tissue factor mediated reaction in a subject.

Group 13, claims 1-24 and 26-29, each drawn in part to an aqueous liquid composition comprising human or bovine factor VII polypeptide having an active site modified by a reaction with a nitrophenylsulfonate, to a first method of making the composition, and to a method of use of the composition in the inhibition of a tissue factor mediated reaction in a subject.

Group 14, claims 1-24 and 26-29, each drawn in part to an aqueous liquid composition comprising human or bovine factor VII polypeptide having an active site modified by a reaction with an isocoumarin, to a first method of making the composition, and to a method of use of the composition in the inhibition of a tissue factor mediated reaction in a subject.

Group 15, claims 1-24 and 26-29, each drawn in part to an aqueous liquid composition comprising human or bovine factor VII polypeptide having an active site modified by a reaction with a coumarin, to a first method of making the composition, and to a method of use of the composition in the inhibition of a tissue factor mediated reaction in a subject.

The inventions listed as Groups 1 through 15 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Each structural modification of a factor VII polypeptide indicated in Groups I-15 requires the use of a separate, special, technical feature in its preparation, whether the synthesis of a primer for mutagenesis at recited amino acid position or the use of particular reaction conditions to covalently bind or to link a recited adduct to an active site. In addition, each separate structural modification requires a separate search in the patent and non-patent literature. Thus the inventions of Groups 1-15 lack a same or corresponding special technical feature.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. The species are as follows:

A. L-Phe-Phe-Arg chloromethyl ketone,
B. D-Phe-Phe-Arg chloromethyl ketone,
C. L-Phe-Pro-Arg chloromethyl ketone,
D. D-Phe-Pro-Arg chloromethyl ketone,
E. L-Glu-Gly-Arg chloromethyl ketone,
F. D-Glu-Gly-Arg chloromethyl ketone,
G. Dansyl-L-Phe-Phe-Arg chloromethyl ketone,
H. Dansyl-D-Phe-Phe-Arg chloromethyl ketone,

I. Dansyl-L-Phe-Pro-Arg chloromethyl ketone,
J. Dansyl-D-Phe-Pro-Arg chloromethyl ketone,
K. Dansyl-L-Glu-Gly-Arg chloromethyl ketone, and
L. Dansyl-D-Glu-Gly-Arg chloromethyl ketone.

The claims are deemed to correspond to the species listed above in the following manner: Claims 1-29 of Group 5 correspond to at least one of the twelve species of reacted peptide chloromethyl ketones. Claims 1-29 of Group 5 are generic with respect to at least one of the twelve species of reacted peptide chloromethyl ketones.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

Each species of peptide chloromethyl ketone has a specific tripeptide sequence and amino-terminal structure that provide a particular degree of inhibitory activity, considered the special technical feature of each, when covalently bound to a factor VII polypeptide in order to modify the polypeptide. Thus the twelve species of adducts of Group 5 lack a same or corresponding special technical feature.

A telephone call was made to Ms. Reza Green on 7 December 2005 to request an oral election to the above restriction requirement, but did not result in an election being made. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you

have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is 571.272.0933 and whose FAX number is 571.273.0933. The examiner can normally be reached Monday through Friday between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisory Primary Examiner, Dr. Kathleen Kerr, can be reached at 571.272.0931. The official FAX number for all communications for the organization where this application or proceeding is assigned is 571.273.8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571.272.1600.

William W. Moore
8 December 2005

NASHAAT T. NASHED PHD.
PRIMARY EXAMINER